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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,894	01/30/2004	Kobi Iki	00167-491001/02-31-0464	4190

7590
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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

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08/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/766,894	Applicant(s) IKI ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20-60 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-7,9,10,13-16,25-30,36,39 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8,11,12,17,20-24,31-35,37,38,40,41 and 43-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/26/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received February 26, 2009, have been fully considered by the examiner. It is noted that claims 3, 5-7, 9, 10, 13-16, 25-30, 36, 39 and 42 remain withdrawn as being directed to a non-elected invention. The following is a complete response to the February 26, 2009 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the rotational connection between the head and the flexible member must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 8, 11, 12, 17, 20-24, 31-35, 37, 38, 40, 41, 43-46 and 50-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no disclosure of a head member that encloses a flexible portion such that the head is free to rotate about the flexible portion as now recited in these claims. It is noted that the word “rotate” does not exist in any form in the original specification. Additionally, it is noted that while the flexible portion (26) does extend into a portion of the head (22) as shown in Figure 4, there is no attachment shown that would support the rotatable connection now claimed. Rather, it appears as though the head may pivot by virtue of the flexibility of the flexible portions (as shown in the figures). Moreover, the lead (40) would prevent the head member from being able to rotate.

Claim Rejections - 35 USC § 102

Claims 1, 8, 11, 12, 17, 20-23, 31, 33-35, 37, 38, 40, 41, 43-47, 49, 51, 53, 55, 57, 58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Haissaguerre et al (6,068,629).

Haissaguerre et al disclose an electrosurgical instrument comprising a shaft (28) having a flexible portion (142,144,154 - Figure 13) and a head (152) coupled to the shaft through the flexible portion. The head is pivotally coupled to the flexible portion (154) as shown in Figure 13C,”and the head includes a planar, non-conductive surface (152) having a plurality of conductive surfaces (160) mounted thereon. The electrodes may be recessed in the head as shown in Figures 6 and 13, or the electrodes may protrude from the head as shown in Figures 9 and 10. The examiner maintains that once deployed, the flexible portion is configured to passively bias the conductive surface towards tissue. The head contains a slot (Figure 13c) about which the head is configured to pivot. The method of using the device to treat tissue is inherent to the structure and is fully disclosed by Haissaguerre et al.

Regarding the newly added limitations, it is again noted that applicant’s specification fails to disclose or show a connection that supports the rotatable nature of the head relative to the flexible portions. Rather, it appears the flexible portions are directly connected to the head thereby making the head pivotable, or rotatable to the extent the flexible members may also rotate (or twist). Haissaguerre et al show flexible portions that are enclosed by a portion of the head member (Figure 13B). The examiner maintains the connection is substantially the same as the connection shown in

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applicant's Figure 4, and that the head is inherently rotatable, to some degree, about flexible portion (154) in a manner that applicant's head member would be rotatable about flexible portions (26).

Regarding newly added claims 51, 53, 55, 58 and 60, the examiner maintains a flexible power lead is coupled to the conductive surfaces, the lead extending through the flexible portions (142,146 – col. 13, lines 28-30).

Regarding newly added independent claim 47, the Haissaguerre et al device comprises the shaft, flexible portion and head portion as addressed above. The limitation “the non-conductive surfaced sized to limit how far the electrically conductive surface can advance into tissue such that the tissue effect is limited to one or more of debriding, smoothing and sealing the tissue” is deemed to be inherently met by Haissaguerre et al. There is no disclosure of what specific dimensions are required to meet such a limitation, nor is there any recitation of the specific size. The non-conductive surface (152) would inherently prevent the conductive surfaces from advancing any further into tissue than the size of the non-conductive surface could allow. And the electrodes are inherently capable of providing any one of debriding, smoothing and sealing of tissue.

Regarding newly added independent claim 58, the examiner maintains that the head is clearly free to pivot relative to the flexible members (142,144) such that the electrode may be maintained in contact with tissue as the head moves.

Claim Rejections - 35 USC § 103

Claims 2, 4, 48, 50, 52, 54, 56 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629).

Haissaguerre et al disclose applicant's invention as addressed previously, but fail to specifically disclose the use of a nitinol or spring wire in the flexible portion. It is noted that Haissaguerre et al clearly disclose a flexible wire member, and also teach of the use of nitinol (col. 8, line 65). The examiner maintains that the use of any well known flexible material, such as nitinol or spring steel, for making the flexible actuator members would have been an obvious design consideration for one of ordinary skill in the art, particularly considering that Haissaguerre et al disclose the use of such materials.

Regarding the specific size limitations regarding the non-conductive and conductive surfaces, it is noted that applicant's specification provides no criticality or unexpected results associated with the particular size limitations. The specific sizes of the head member and its conductive portions of the Haissaguerre et al device are deemed obvious design considerations, and one of ordinary skill in the art would be fully capable of selecting appropriate sizes as deemed necessary for a given procedure.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629) in view of the teaching of Hall et al (6,290,699).

Haissaguerre et al fail to disclose the particular "T-shaped" electrode recited in this claim.

Hall et al disclose another electrosurgical device that includes a head member (140) supported on an elongate member (120), the head member having a plurality of electrodes (130) mounted on a non-conductive portion of the head member. In particular, Hall et al teach that the electrodes on the head member may be provided with a variety of shapes, as shown in Figures 2-9. The examiner maintains that to have provided any desired electrode pattern would be an obvious design choice. It is further noted that applicant's specification is void of any criticality or unexpected result associated with the particular shape for the electrode structure.

To have provided the Haissaguerre et al device with electrodes formed on the head member in any desired shape, including a "T-shape", to treat a particular region of interest is deemed an obvious design modification for one of ordinary skill in the art, particularly since Hall et al teach that it is known to provide various electrode shapes as a matter of design choice on an analogous device.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629) in view of the teaching of Parins et al (5,125,928).

Haissaguerre et al disclose an elongate member, but fail to specifically disclose a sheath provided for covering the flexible portion of the head for delivery of the ablation head to tissue.

Parins et al disclose another RF device that includes a shaft (62) and a pivotally mounted head (80) mounted to the shaft. Electrodes are provided on the head member for treating tissue. Further, Parins et al teach that it is known to provide a sheath

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member (60) which covers the flexible portion of the shaft and the head member prior to deployment to assist in delivering the device to a tissue site.

To have provided the Haissaguerre et al device with a sheath member to cover the head during insertion of the device to a treatment site would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Parins et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims specify: a shaft, a flexible portion, and a head coupled to the shaft through the flexible portion and pivotably coupled to the

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flexible portion, the head including a non-conductive surface and an electrically conductive surface, wherein the flexible portion is configured to bias the non-conductive surface and the electrically conductive surface towards a tissue surface.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims specify: a shaft, a flexible portion, and a head coupled to the shaft through the flexible portion and pivotably coupled to the flexible portion, the head including a non-conductive surface and an electrically conductive surface, wherein the flexible portion is configured to bias the non-conductive surface and the electrically conductive surface towards a tissue surface. Furthermore, it would be obvious, if not inherent, for the non-conductive surface of 10/999230 to be adjacent at least a portion of the electrically conductive portion, since the non-conductive portion limits penetration of the electrically conductive surface into the tissue surface.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 43 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No.

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10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims specify: a shaft, a resiliently flexible portion, and a head coupled to the shaft through the resiliently flexible portion, the head being pivotably coupled to the resiliently flexible portion, the head including a substantially planar tissue contact surface including a non-conductive portion and an electrically conductive portion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 4, 8, 11-12, 17, 20-24, 31-35, 37-38, 40-41, and 43-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 12 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the more specific claims of 10/999230 encompass the broader claims in 10/766894. In addition, the "resiliently flexible portion" and "to passively bias" of 10/999230 are elements that are obvious and well-known to one of ordinary skill in the art. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are not persuasive.

Regarding the newly added limitations to the independent claims, the examiner maintains as asserted above that there is insufficient support in the specification to support the rotational relationship between the head and the flexible member. Further, the examiner maintains that the connection of the Haissaguerre et al flexible members to the head portion are substantially identical to that shown and disclosed in applicant's specification and would therefore allow for the same type of rotation.

The newly added claims have been addressed in the above rejections. It is noted that applicant has not addressed the double patenting rejections which are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
August 18, 2009